

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
_____	)	
THIS DOCUMENT RELATES TO:	)	
	)	
SHEILA BROWN, et al.	)	
	)	CIVIL ACTION NO. 99-20593
v.	)	
	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8525

Bartle, C. J.

September 2, 2010

Lennie M. Morgan ("Ms. Morgan" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the Show Cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Mark A. Levinson, M.D., F.A.C.C. Dr. Levinson is no stranger to this litigation. According to the Trust he has signed in excess of 2,076 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated August 5, 2002, Dr. Levinson attested in Part II of claimant's Green Form that Ms. Morgan suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of

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2. (...continued)

not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

50% to 60%.<sup>3</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$538,973.<sup>4</sup>

In the report of claimant's echocardiogram, Dr. Levinson indicated that claimant had moderate mitral regurgitation, which he measured at 22%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In April, 2003, the Trust forwarded the claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Penkala explained that "[t]he RJA has been overestimated in this study. The traced area incorporates some low velocity signals and the traced areas are inconsistent. The

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3. Dr. Levinson also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

RJA appears to occupy [less than] 20% of the LAA and therefore I grade the [mitral regurgitation] as mild."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Morgan's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>5</sup> In contest, claimant argued that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because three cardiologists found that she had moderate mitral regurgitation on three separate echocardiograms. In support of this argument, claimant submitted an affidavit of Terry B. Tri, M.D., who performed claimant's March 8, 2001 echocardiogram that claimant received under the Trust's Screening Program.<sup>6</sup> Dr. Tri opined that claimant's March 8, 2001 echocardiogram demonstrated "mild to moderate mitral regurgitation but closer to moderate," and that Ms. Morgan had "moderate mitral regurgitation at least as defined by Singh, in accordance with the Class Action Settlement Agreement." Dr. Tri

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Morgan's claim.

6. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

also stated that he reviewed claimant's August 5, 2002 echocardiogram, which he said showed moderate mitral regurgitation, and that he "disagree[d] with the auditing cardiologist that the RJA has been overestimated ... and further disagree[d] that the traced area incorporates some low velocity signals and the traced areas are inconsistent." Claimant also submitted an affidavit from Richard J. Nijem, M.D., who performed a subsequent echocardiogram on Ms. Morgan on December 27, 2007. Dr. Nijem stated that claimant's level of mitral regurgitation on the subsequent echocardiogram was moderate at 24%.

The Trust then issued a final post-audit determination, again denying Ms. Morgan's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Morgan's claim should be paid. On January 12, 2006 we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5940 (Jan. 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 6, 2006. Under the Audit Rules, it is within the Special Master's discretion to

appoint a Technical Advisor<sup>7</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Morgan reasserts the same arguments that she made in contest; namely that there is a reasonable medical basis for her claim because three cardiologists confirmed that she had moderate mitral regurgitation on three separate echocardiograms. Claimant also contends that the auditing cardiologist should have provided exact measurements of Ms. Morgan's level of mitral regurgitation and that Dr. Penkala's statement that the RJA "'appears to occupy less than 20% of the LAA'" is an extremely vague statement. (emphasis in original.) According to claimant, "[Dr.] Penkala's opinions, which appear to be more like educated guesses, do not carry substantial weight when considered in light of the fact that she was hired and paid by the Trust to examine [claimant's] echocardiogram."<sup>8</sup>

In response, the Trust contends that the auditing cardiologist performed the audit in accordance with the Settlement Agreement, and that "eyeballing" the level of regurgitation is well accepted in the world of cardiology. The Trust further states that the additional echocardiogram reports and affidavits submitted by claimant are insufficient to establish a reasonable medical basis for finding that her

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8. In addition, claimant argues that she should receive Matrix Benefits because the Trust did not timely issue a final post-audit determination. We disagree. As we previously discussed in PTO No. 6339, "we are unwilling to order payment on an uncompensable claim solely based on an 'out of time' argument, without, at a minimum, some showing of prejudice." PTO No. 6339 at 13 n.10 (May 25, 2006).

echocardiogram of August 5, 2002 demonstrated moderate mitral regurgitation. Finally, the Trust argues that Dr. Tri's participation in the Screening Program does not entitle his opinions to any additional weight in the show cause process.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Morgan had moderate mitral regurgitation. Specifically, Dr. Vigilante stated that:

Only mild mitral regurgitation was noted on this study. The mitral regurgitant jet was most impressively seen in the apical four chamber view.... I measured the LAA and RJA in those cardiac cycles in which the mitral regurgitation jet appeared most impressive. The RJA/LAA ratio was less than 12% on those views in which the mitral regurgitation appeared most impressive. The RJA/LAA ratio was less than 10% in the apical two chamber view. I reviewed the measurements of the RJA made by the sonographer on the tape. These measurements are inaccurate and included low velocity, non-mitral regurgitant flow. The true RJA was much less than those measurements made by the sonographer. The LAA of 15.72 cm<sup>2</sup> measured by the sonographer was also inaccurate. I measured the LAA to be 17.3 cm<sup>2</sup> at 8:32:50 on the tape.

In response to the Technical Advisor Report, claimant states that the Technical Advisor stated that he saw parasternal long-axis views on the echocardiogram while Dr. Penkala noted that the parasternal long-axis view was not available. Claimant argues, therefore, that either frames were inserted into the tape, or it is an entirely different echocardiogram. As such,



claimant suggests that the "chain of custody" for the echocardiogram of attestation be investigated.<sup>9</sup>

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately contest the findings of the Technical Advisor. Specifically, claimant does not refute Dr. Vigilante's assessment that her RJA/LAA ratio was less than 12% in those cycles in which the mitral regurgitation appeared most severe. Claimant also never identified any particular error in Dr. Penkala's measurements or conclusions. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying and substantiating any specific errors is insufficient to meet a claimant's burden of proof. On this basis alone claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

We also disagree with claimant that the opinions of Dr. Tri, Dr. Nijem, and Dr. Levinson provide a reasonable medical basis for Dr. Levinson's representation that Ms. Morgan had moderate mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include (1) failing to review multiple loops and still frames;

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9. Claimant further argues that there is a "conflict of interest" because the Special Master's name appeared on correspondence she received from the Office of Interim Claims Administrators regarding the Nationwide Class Action Settlement with American Home Products Corporation. We do not agree with claimant that this creates a conflict of interest.

(2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, both Dr. Penkala and Dr. Vigilante identified deficiencies in the measurements made by the sonographer. Specifically, Dr. Penkala determined that claimant's RJA was "overestimated" because "[t]he traced area incorporates some low velocity signals." In addition, Dr. Vigilante observed that the measurements were "inaccurate and included low velocity, non-mitral regurgitant flow." Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.<sup>10</sup>

Finally, we disagree with claimant that Dr. Penkala was required to provide a specific measurement of Ms. Morgan's level

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10. We also reject claimant's argument that there is a reasonable medical basis for her claim because Dr. Vigilante observed parasternal long-axis views on claimant's echocardiogram while, according to claimant, Dr. Penkala did not. Notably, Dr. Penkala's statement regarding her inability to assess parasternal long-axis views on claimant's echocardiogram of attestation relates to her review of claimant's left atrial dimension, and not claimant's level of mitral regurgitation.

of mitral regurgitation rather than provide a visual measurement. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." PTO No. 2640 at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.<sup>11</sup>

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Morgan's claim for Matrix Benefits.

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11. Claimant's argument also fails because the Technical Advisor, although not required to, made specific measurements of the level of mitral regurgitation demonstrated on claimant's August 5, 2002 echocardiogram, which further establish that claimant is not entitled to Matrix Benefits.